Remarks

Applicant appreciates the thorough examination of the present application as evidenced by the final Office Action dated November 11, 2006 (hereinafter, the "Final Action."). Claims 23, 26-35 and 45-51 stand finally rejected in the Final Action under 35 U.S.C. §103(a) as being obvious in view of the combination of Dobbie, "Separation of Peritoneal Surfaces Through the Maintenance of an Artificial Ascites as a Preventative of Peritoneal Adhesions." Abstract, 4th Peritoneum and Peritoneal Access Meeting, September 16-19, 1997 (hereinafter, "the Dobbie abstract") in view of U.S. Patent No. 4,886,789 to Milner (hereinafter, "Milner"). Upon entry of the present Amendment, Claims 23, 26-35 and 45-83 are pending in the present application, and Applicant respectfully submits that these claims are patentable for at least the reasons presented below.

I. Interview Summary

Applicant is grateful to Examiner Everett White, Supervisory Primary Examiner Shaojia A. Jiang and Training Quality Assurance Specialist/Supervisory Primary Examiner Yvonne L. Eyler for participating in the interview at the United States Patent and Trademark Office conducted on April 24, 2007 (hereinafter, the "interview") with Applicant's U.S. legal representative Shawna Cannon Lemon and Applicant's European representatives Dr. Elizabeth Peers and Ms. Alexis Harper.[1]

The participants discussed the pending application and additional data provided by Dr. Peers directed to methods of reducing post-operative adhesions.

In view of the helpful and constructive dialog expressed during this interview resulting in the indication that an agreement with respect to the claims was reached, Applicant sets forth herein amendments and remarks that support the nonobviousness of the pending claims.

II. Claim Rejections Under 35 U.S.C. § 103

As noted above, Claims 23, 26-35 and 45-51 stand rejected under 35 U.S.C. § 103(a) as being obvious over the Dobbie abstract in view of Milner. *See* Final Action, pages 2 and 3.

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[1] Examiners Roy Issac and Eric Olson were also present to observe the interview.

As noted by Dr. Peers during the interview, the Dobbie abstract mentions the use of a ***peritoneal dialysis*** solution post-operatively to reduce the risk of abdominal adhesions. As further noted by Dr. Peers, Milner merely describes procedures involving ***peritoneal dialysis*** and compositions for use during the ***peritoneal dialysis*** process. The cited references, neither alone nor in combination, teach or suggest a method of reducing post-operative adhesions as recited in the pending claims. Applicant submits concurrently herewith a Declaration Under 37 C.F.R. §1.132 of Dr. Elizabeth Peers, MA. PhD (hereinafter, the "Peers Declaration"), which further sets forth the nonobviousness of the pending claims in view of the cited references.

As discussed in the accompanying Peers Declaration, there are clear fundamental distinctions between ***peritoneal dialysis*** and ***methods of adhesion reduction*** as disclosed in the present application. *See* figures at Tab 2 and the table at Tab 3. For example, peritoneal dialysis involves, among other things: (a) continuous flux of fluids in and out, (b) each "dwell" draws in waste products and excess fluid, (c) "dirty" fluid is drained out and replaced with clean fluid at each "exchange," and (d) peritoneal dialysis is a patient-managed, daily, chronic and/or long-term treatment. In contrast, the methods of adhesion reduction described in the present application involve, among other things: (a) administration by a healthcare professional, typically in an operating room or other medical setting, (b) is not a daily or long-term treatment, and (c) the aqueous solution serves as a reservoir.

Regarding the fluid reservoir aspect of the present invention, the graph at Tab 4 of the Peers Declaration demonstrates the fluid reservoir mode of action of the present invention with regard to adhesion formation as a function of volume over time. In particular, the graph shows that the volume of fluid in the peritoneal cavity remained steady for up to 48 hours. Thereafter, the volume declines slowly, with approximately half the administered volume remaining at 96 hours. In contrast, under the same conditions, a glucose peritoneal dialysis solution and a normal saline solution were almost fully absorbed after 24 hours.

In summary, and as believed by Applicant to have been noted at the conclusion of the interview, at least each of the following aspects of the present invention (individually and in no particular order) were novel and nonobvious over the technology described in the cited references: (a) the post-operative nature, (b) the difference in volume used in peritoneal dialysis in contrast to the volume used in the adhesion reduction methods, (c) the lack of

long-term, chronic use of the aqueous formulation associated with the adhesion reduction methods, and (d) the reservoir nature of the aqueous solution in the adhesion reduction technology, i.e., the fluid is not removed in the current methods of reducing post-operative adhesions.

III. Claim Amendments and New Claims

In order to further clarify the distinctions between peritoneal dialysis and the current adhesion reduction technology, Applicant has amended the claims and presented new claims herein consistent with discussions during the interview and further in view of Applicant's review of the pending application.

A. Claim Amendments

Independent Claim 23 now recites a method of reducing the incidence of post-operative adhesions. As discussed during the interview, the combination of the Dobbie abstract and Milner does not teach or suggest a method of reducing "post-operative" adhesions. Support for this claim amendment can be found in the application as originally filed, for example, the Abstract, among other places.

Independent Claim 51 now recites a method of reducing the incidence of post-operative adhesions and further recites that the aqueous formulation is a solution in the body cavity, remains in the body cavity for at least 2 days and is not removed. As discussed during the interview, the combination of the Dobbie abstract and Milner does not teach or suggest a method of reducing "post-operative" adhesions including, among other things, administering an aqueous formulation that remains in the body cavity for at least 2 days and is not removed. Support for these claim amendments can be found in the application as originally filed, for example, Evidence in Support of the Invention starting at page 7 (hereinafter, "the experimental section"), among other places.

Several of the previously presented dependent claims have been amended to recite that the "aqueous formulation" remains in the body cavity. This recitation has been added in order to clarify the claim language. Applicant further submits that "by remaining in the body cavity" it is understood that the aqueous formulation comprising the polysaccharide dextrin is subject to a degree of metabolism/degradation while in the body cavity as noted in the present application on page 4, line 10-13.

B. New Claims

Independent Claim 57 is directed to a method of reducing the incidence of post-operative adhesions including "allowing the aqueous formulation to remain in the body cavity for at least 2 days, wherein the aqueous formulation is not removed from the body cavity." As discussed during the interview, the combination of the Dobbie abstract and Milner does not teach or suggest a method of reducing "post-operative" adhesions including, among other things, allowing the aqueous formulation to remain in the body cavity for at least 2 days, wherein the aqueous formulation is not removed from the body cavity. Instead, the cited references teach a procedure that involves a long-term, chronic, patient-managed procedure characterized by continual fluid exchange by administering "clean" fluid and removing fluid containing waste, toxins and other biological by-products. Support for this new claim can be found in the application as originally filed and in the support for the amendment to Claim 51 as discussed above.

Independent Claim 67 is directed to a method of reducing the incidence of post-operative adhesions including administering the aqueous formulation "under surgical conditions and the aqueous formulation remains in the body cavity and is not removed." As discussed during the interview and for at least the reasons previously discussed herein, the combination of the Dobbie abstract and Milner does not teach or suggest a method of reducing post-operative adhesions including, among other things, administering the aqueous formulation under surgical conditions where the aqueous formulation remains in the body cavity and is not removed. Support for this new claim can be found in the application as originally filed, for example, at page 1, lines 1-9 and the experimental section, among other places.

Independent Claim 77 is directed to a method of reducing the incidence of post-operative adhesions including "introducing into the body cavity a composition comprising less than 2000 ml of an aqueous formulation." As discussed during the interview, the combination of the Dobbie abstract and Milner does not teach or suggest a method of reducing post-operative adhesions including introducing into the body cavity a composition comprising less than 2000 ml of an aqueous formulation. Instead, the cited references teach the peritoneal dialysis procedure as discussed herein and further teach the addition of greater volumes of fluid that are added and removed from the patient. Support for this new claim can

be found in the application as originally filed, for example, at page 4, lines 24-26 and the experimental section, among other places.

Applicant has added several new dependent claims. The new dependent claims include recitations that were present in the original and/or previously presented dependent claims. However, there are several dependent claims that include recitations noting that the composition is introduced when the operation or surgical condition is an abdominal operation or surgery (Claims 52, 59, 69 and 78) or a gynecological operation or surgery (Claims 53, 60, 70 and 79). Support for these new claims can be found in the application as originally filed, for example, at page 1, lines 1-9 and the experimental section, among other places.

Applicant respectfully submits that no new matter is added upon entry of the claim amendments and new claims, and Applicant respectfully requests entry and allowance thereof.

IV. Objective Indicia of Nonobviousness/Secondary Considerations

In addition to the distinctions between peritoneal dialysis and the methods of adhesion reduction of the present invention, there exists objective indicia consistent with the Manual of Patent Examining Procedure (MPEP) § 716.01(a) that direct one away from a finding of obviousness of the pending claims.

In particular, adhesions are the single greatest complication of surgery. Young et al. Fertility and Sterility **84**: 1450-1456 (2005). 93% of patients undergoing abdominal surgery are affected by adhesions. Menzies and Ellis. Annals Royal College of Surgeons of England **72**:60-63 (1990). Adhesions may result in infertility, bowel obstruction and chronic pelvic pain. Accordingly, adhesions may have a significant impact on health-care costs, time and quality of life. Aspects of the adhesion reduction technology described in the present application and recited in the pending claims are currently marketed by Baxter Healthcare Corporation as Adept®. Adept® is a clinically effective product shown to reduce the incidence of adhesions after gynecological laparoscopic surgery, and thus, Adept® presents a scientific advance in surgical procedures. Data in support of this statement as well as the package insert information for Adept® can be found at Tabs 5 and 6 of the Peers Declaration. Further, and quite notably, Baxter licensed the dextrin peritoneal dialysis solution in 1996. Baxter has recognized the fundamental difference between the peritoneal dialysis solution

and the adhesion reduction solution and is now a licensee of the adhesion reduction technology.

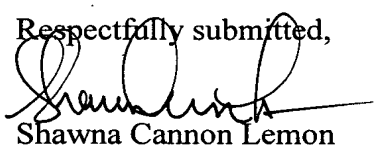
Accordingly, Applicant respectfully submits that the remarks presented herein address the issue of obviousness in view of the combination of the Dobbie abstract and Milner, and the secondary considerations discussed herein further support the nonobviousness of the present invention to the scientific and medical community in general. Therefore, Applicant respectfully submits that the pending claims are patentable.

Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests that all outstanding rejections to the claims be withdrawn and that a Notice of Allowance be issued in due course.

The Examiner is invited and encouraged to contact the undersigned directly if such contact will expedite the prosecution of the pending claims to issue. In any event, any questions that the Examiner may have should be directed to the undersigned, who may be reached at (919) 854-1400.

Respectfully submitted,



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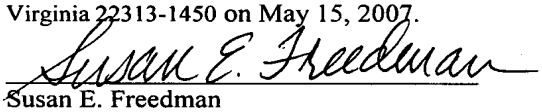

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Date of Signature: May 15, 2007